Expanding Access to PrEP: Financing and Coverage Considerations

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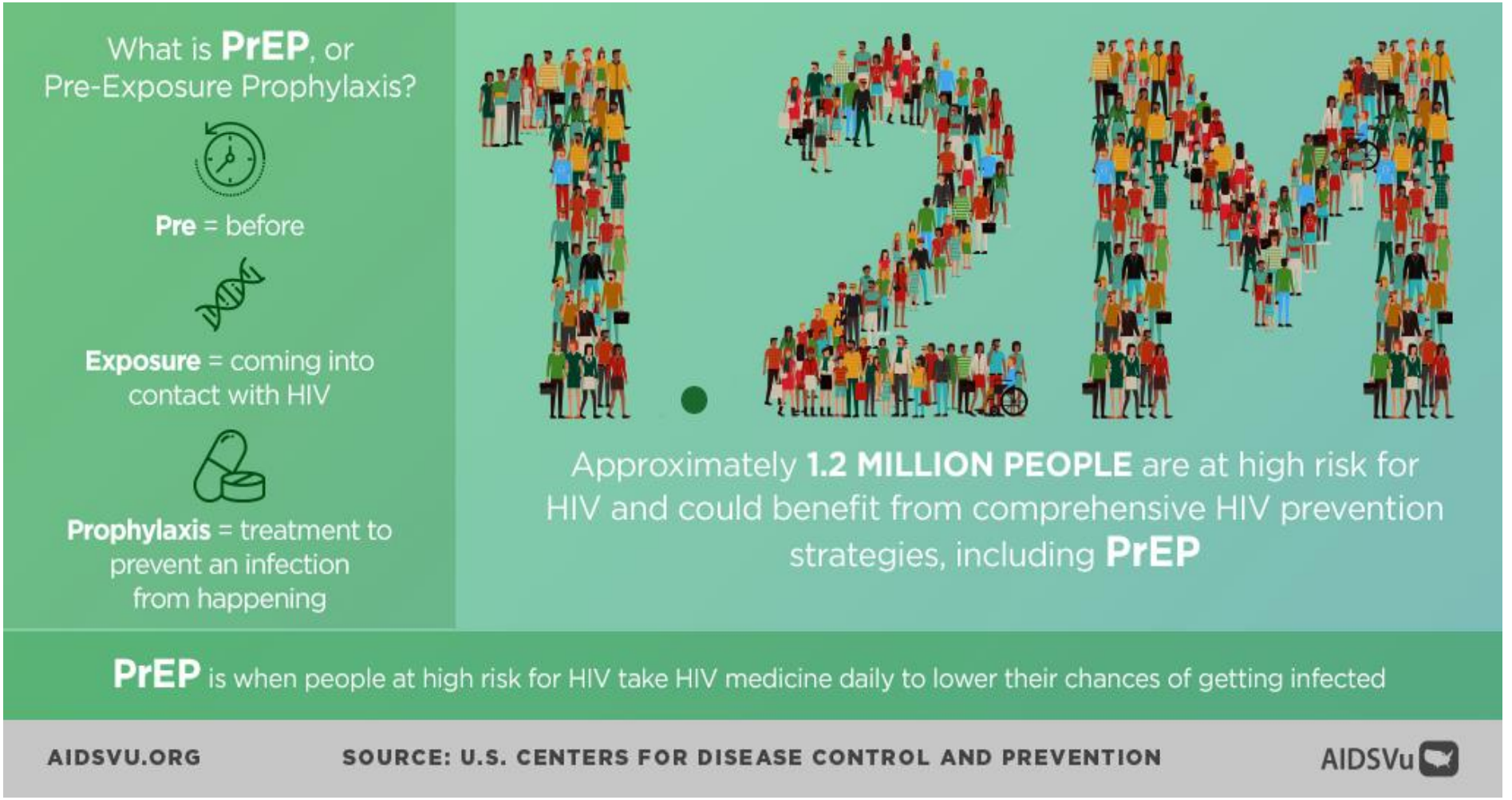
North Dakota 2019 HIV/STD/TB/Hepatitis Symposium

Presentation Road Map

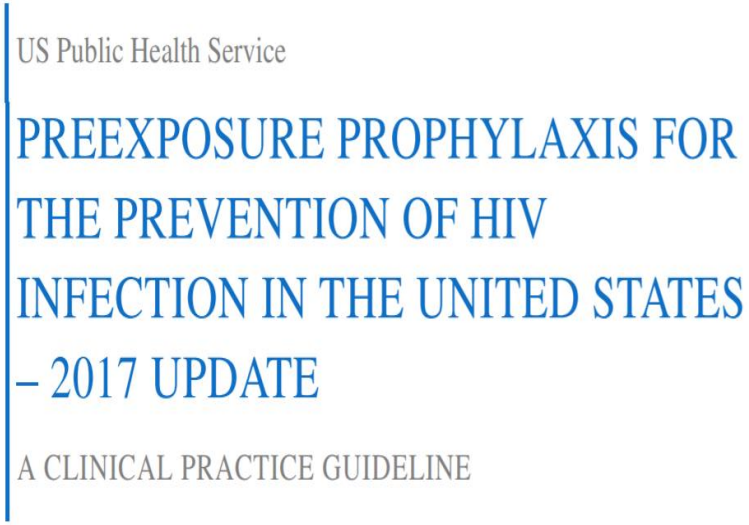
- PrEP Introduction
- PrEP Pipeline Overview
- PrEP Coverage and Cost Landscape
- Coverage Policies Impacting PrEP Access and Affordability
- Considerations for Sustainable PrEP Payment and Delivery Models

PrEP Introduction

What is PrEP


What is PrEP, or Pre-Exposure Prophylaxis?
Pre = before
Exposure = coming into contact with HIV
Prophylaxis = treatment to prevent an infection from happening
1.2M
Approximately 1.2 MILLION PEOPLE are at high risk for HIV and could benefit from comprehensive HIV prevention strategies, including PrEP
PrEP is when people at high risk for HIV take HIV medicine daily to lower their chances of getting infected
AIDSVU.ORG
SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION
AIDSVu

CDC Clinical Guidelines for PrEP



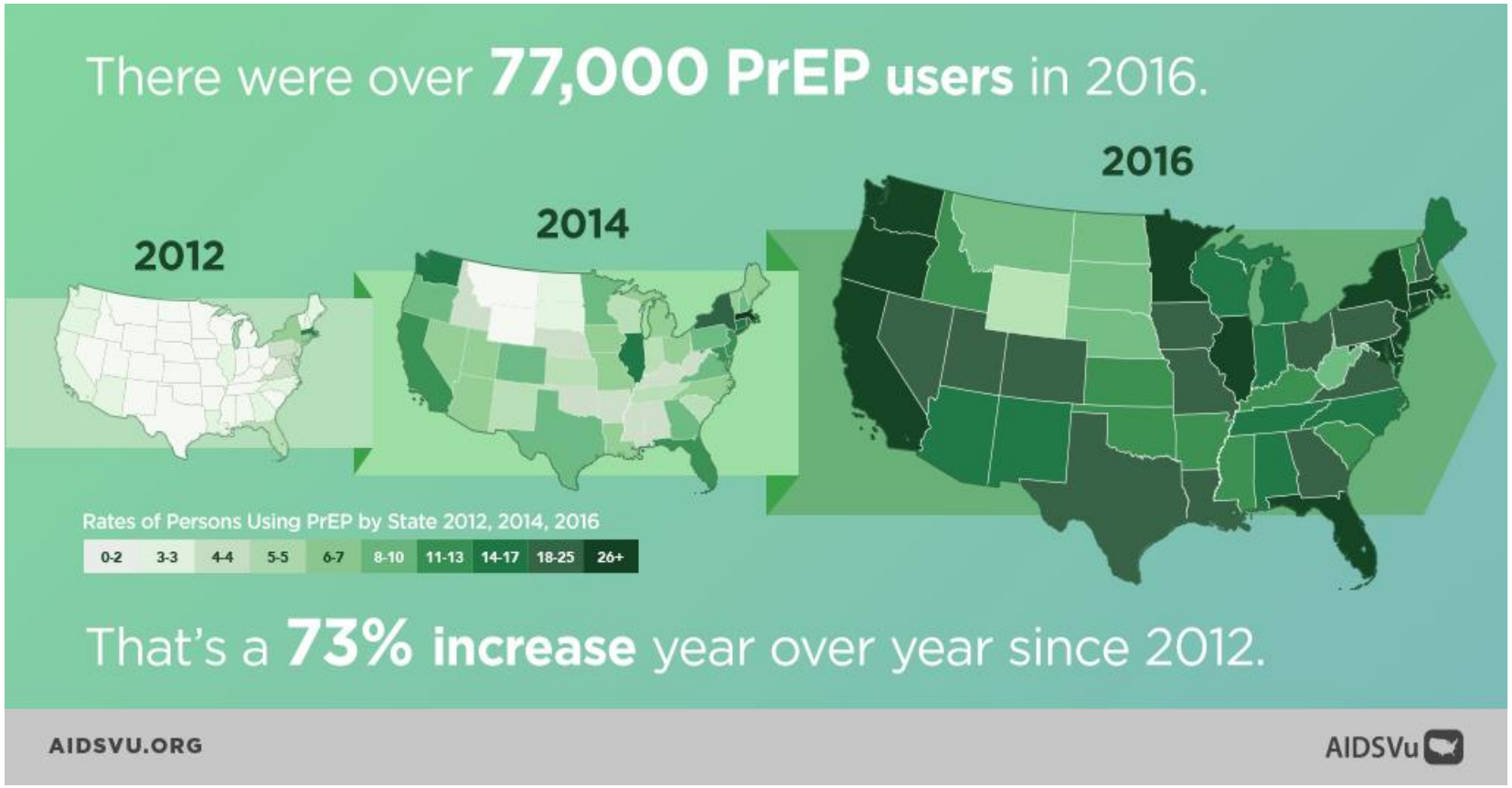
- CDC PrEP Clinical Guidelines include:
  - Populations indicated for PrEP (gay and other MSM, heterosexual men and women, and people who use drugs who are at substantial risk for HIV acquisition)
  - Clinical recommendations for prescribing PrEP, including recommended HIV and STD screening and renal functioning assessment at initiation and every three months

Clinical Guidelines available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

CDC Guidelines: Who Is PrEP For?

	Men Who Have Sex with Men	Heterosexual Women and Men	Persons Who Inject Drugs
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI† High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI‡ High number of sex partners History of inconsistent or no condom use Commercial sex work In high HIV prevalence area or network	HIV-positive injecting partner Sharing injection equipment
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 3-6 months, test for bacterial STIs		
	Do oral/rectal STI testing	For women, assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

PrEP Prescribing Patterns



But it's not nearly enough…

PrEP Disparities

- According to 2016 AIDSVu data and 2015 CDC data, PrEP prescriptions varied significantly based on gender, geography, and race/ethnicity:
  - Only ~7% of the 1.2 million people eligible for PrEP are actually using it as a prevention tool
  - Among Black and Latino gay and other men who have sex with men, only 1% and 3% are using PrEP respectively
  - Women had far lower rates of PrEP prescriptions (93% of all PrEP users in 2016 were men)
  - The U.S. South, which accounted for half of all new HIV diagnoses in 2016, had lower rates of PrEP prescriptions

PrEP Pipeline Overview

PrEP Pipeline: At-a-Glance

Product	Route of Administration	Status
TDF/FTC	Oral	Single generic competitor in Sept 2020; multiple competitors beginning March 2012
TAF/FTC		Phase III (Phase I-II in African women)
RAL/3TC		Phase IV
Cabotegravir	Long-acting	Phase III
Dapivirine	Ring	Phase III/FDA review (ring); 3-month ring and rectal gel in development
Tenofovir		Phase I
Dapivirine or tenofovir + levonorgestrel		Phase I
Tenofovir, TAF/EVG, IQP-0528, Griffithsin, PC-1005, DS-003	Vaginal or rectal inserts, enemas, and tablets	Pre-clinical – Phase I

PrEP Coverage and Cost Landscape

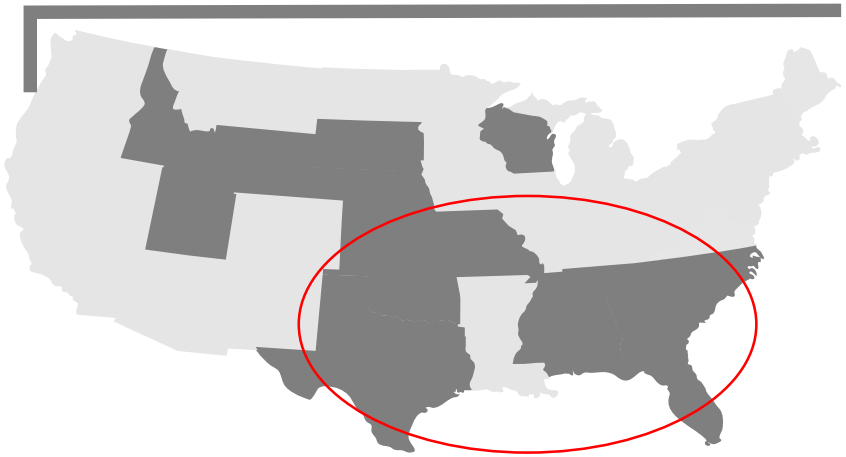
Payment and Delivery Barriers to PrEP

Payment & Delivery Conundrum

- CDC funds may not be used for PrEP medication (policy)
- Ryan White HIV/AIDS Program cannot pay for the medication (statutorily)
- Clinical expertise necessary for appropriate PrEP access

Medicaid Expansion

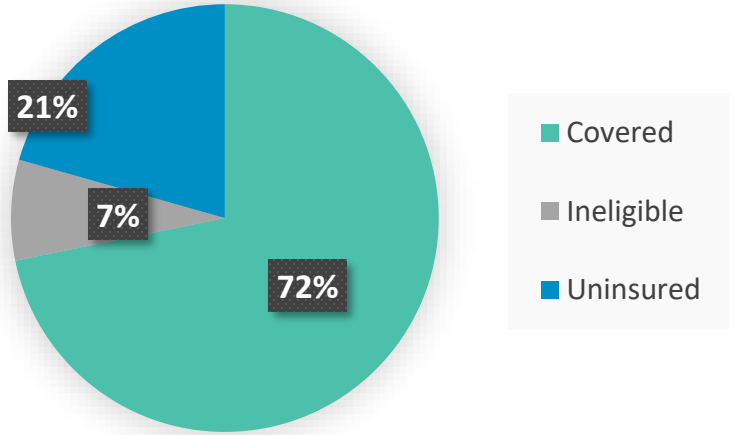
- 17 states have still not expanded Medicaid



High Cost

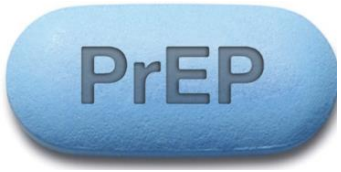
- Without 340B discount, the drug cost is prohibitively expensive for many public health programs
- High co-payments/co-insurance for a specialty-tier medication

Coverage for PrEP Candidates



Source: Smith DK et. al. JAIDS 76.5 (2017)

Getting the Cost and Access Incentives Right



Family planning clinics

PrEP DAPs (state HD)

Private providers

Local health departments (STD clinics)

Community health centers

Uninsured populations (non-340B discount)

Underinsured populations

Insured populations

Uninsured populations (340B discount)

Underinsured populations

Insured populations

Manufacturer Co-pay and Patient Assistance Programs & Donation Program

PrEP Components and Costs

PrEP Components	Cash Price*
Medication (Truvada is only FDA-approved medication for PrEP currently)	~$1,700/month (Wholesale Acquisition Cost, no discount); ~$440/month (340B Price)
Lab costs** (at PrEP initiation and every three months) • Baseline HIV test • HBV tests (at initiation only) • Metabolic panel/creatine test • Gonorrhea and Chlamydia screening • Syphilis screening	~$291 to $3,955
Physician visit (at initiation and every three months)	~$60 to $177 per visit

** Above costs are estimates, the cash price of services varies significantly depending on geography and provider. Many providers provide lab and clinical services to uninsured patients at a reduced rate.*

*** Providers should refer to the CDC PrEP Clinical Guidelines for specific lab recommendations based on patient risk and other factors.*

Source: Whitman, et al, Costs of Providing PrEP for HIV Prevention: Estimates from a Community Health Center, (Abstract PS3-44, 39th SMDH, 2017).

Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms…

	Drug Access	PrEP Clinical Visits & Lab Costs	Counseling and Linkage
Uninsured	Manufacturer Patient Assistance Program PrEP Drug Assistance Programs or "PrEP DAPs" (state funded) Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings	PrEP DAPs (state funded) CDC prevention funds to pay for HIV/STD testing Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings	PrEP DAPs (state funded) CDC prevention grants and 340B savings Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings
Insured	Covered by payers; co-pay assistance through manufacturer assistance program	Largely covered, but with patient co-pays PrEP DAPs pay for lab/clinical visit co-pays (state funded)	Not well covered by public or private insurance

Patient and Co-pay Assistance Programs

Patient Assistance Programs			
Program	Clinical Visits & Labs	Health Insurance	Income Eligibility
Gilead Patient Assistance Program	Not covered	Uninsured	500% FPL

Co-pay Assistance Programs

Co-pay Assistance Programs				
Program	Medication Copay Max	Clinical Visits & Labs	Health Insurance	Income Eligibility
Gilead Advancing Access Copay	$7,200/yr	Not covered	Private health plans	Any income
Patient Advocate Foundation	$7,500/yr	Not covered	Plans covering Truvada	400% FPL
Patient Access Network Foundation	$8,000/yr	Covered (limited)	Medicare	500% FPL

State PrEP Assistance Programs

STATE	DRUG ASSISTANCE		CLINICAL VISITS AND LAB TEST ASSISTANCE	PATIENT INCOME LIMIT
	COPAY ASSISTANCE	MEDICATION ASSISTANCE		
California	Yes	Yes	Any participating provider	Up to 500%
Colorado	Yes	Yes	Any participating provider	Below 500%
District of Columbia	Yes	No	Local health department clinics	Up to 500%
Florida	No	Yes*	Local health department clinics	No threshold
Illinois	Yes	No	Select grantees	No threshold
Massachusetts	Yes	No	Select grantees	Up to 500%
New York State	No	No	Any participating provider	Up to 435%
Ohio	Yes	Yes	Any participating provider	Below 300%
Virginia	No	Yes*	Local health departments and contracted providers	No Threshold
Washington State	Yes	Yes	Any participating provider	No Threshold

340B Models for PrEP

Community Health Centers	• Reach into some (but not all) communities at high risk for HIV • 340B savings to fund services for uninsured
STD Clinics	• Deep reach into communities at high risk for HIV • 340B savings to fund services for uninsured • Start-up funding needed (cannot use CDC grant to purchase drug)
Family Planning Clinics	• Reach into communities at high risk for HIV, particularly women • 340B savings to fund services for uninsured

Ending the Epidemic Initiative

GOAL:

75% reduction in new HIV infections in 5 years and at least **90%** reduction in 10 years.

Our goal is ambitious and the pathway is clear – employ strategic practices in the *places* focused on the right *people* to:

Diagnose all people with HIV as early as possible after infection.

Treat the infection rapidly and effectively to achieve sustained viral suppression.

Protect people at risk for HIV using potent and proven prevention interventions, including PrEP, a medication that can prevent HIV infections.

Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

HIV HealthForce will establish local teams committed to the success of the Initiative in each jurisdiction.

Ending the Epidemic Initiative

The Initiative will target our resources to the 48 highest burden counties, Washington, D.C., San Juan, Puerto Rico, and 7 states with a substantial rural HIV burden.

Geographical Selection:
Data on burden of HIV in the US shows areas where HIV transmission occurs more frequently. More than 50% of new HIV diagnoses* occurred in only 48 counties, Washington, D.C., and San Juan, Puerto Rico. In addition, 7 states have a substantial rural burden – with over 75 cases and 10% or more of their diagnoses in rural areas.

Ending the HIV Epidemic | www.HIV.gov

Gilead PrEP Donation and Settlement

- On May 9, 2019, Gilead Sciences announced they will donate PrEP medication (Truvada and then Descovy) for up to 200,000 individuals per year for up to 11 years to assist in the ETE 2030 initiative
  - Details are forthcoming, but Gilead intends to make PrEP available to uninsured individuals, largely through community health centers
- Gilead also announced details of a settlement agreement reached with Teva Pharmaceuticals in 2014, allowing Teva to produce generic TDF/FTC in September 2020 (6 month exclusivity period)

PrEP Coverage Policies

USPSTF Draft Grade A Recommendation

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition	**A**

- ACA mandates that private insurance plans and Medicaid expansion programs cover preventive services with a USPSTF A or B rating **at no cost**
- Plans must adopt in the plan year that begins at least one year following the final USPSTF recommendation

Implementation Considerations

Access to the medication

- Potential for UM to be used in discriminatory (e.g. prior authorization)
- Need to anticipate a different PrEP medication landscape in the next 1-2 years (e.g. generic PreP, long-acting injection)

Access to PrEP services beyond medication

- Includes HIV, hepatitis, and STI testing at initiation and every three months as well as follow-up provider appointment every three months, all of which should be covered without cost sharing

Implementation Considerations

Identifying Individuals at high risk

- Includes heterosexual people, men who have sex with men, and transgender people with a partner living with HIV or other additional risk factors, and individuals who inject drugs

Accounting for different delivery systems for PrEP

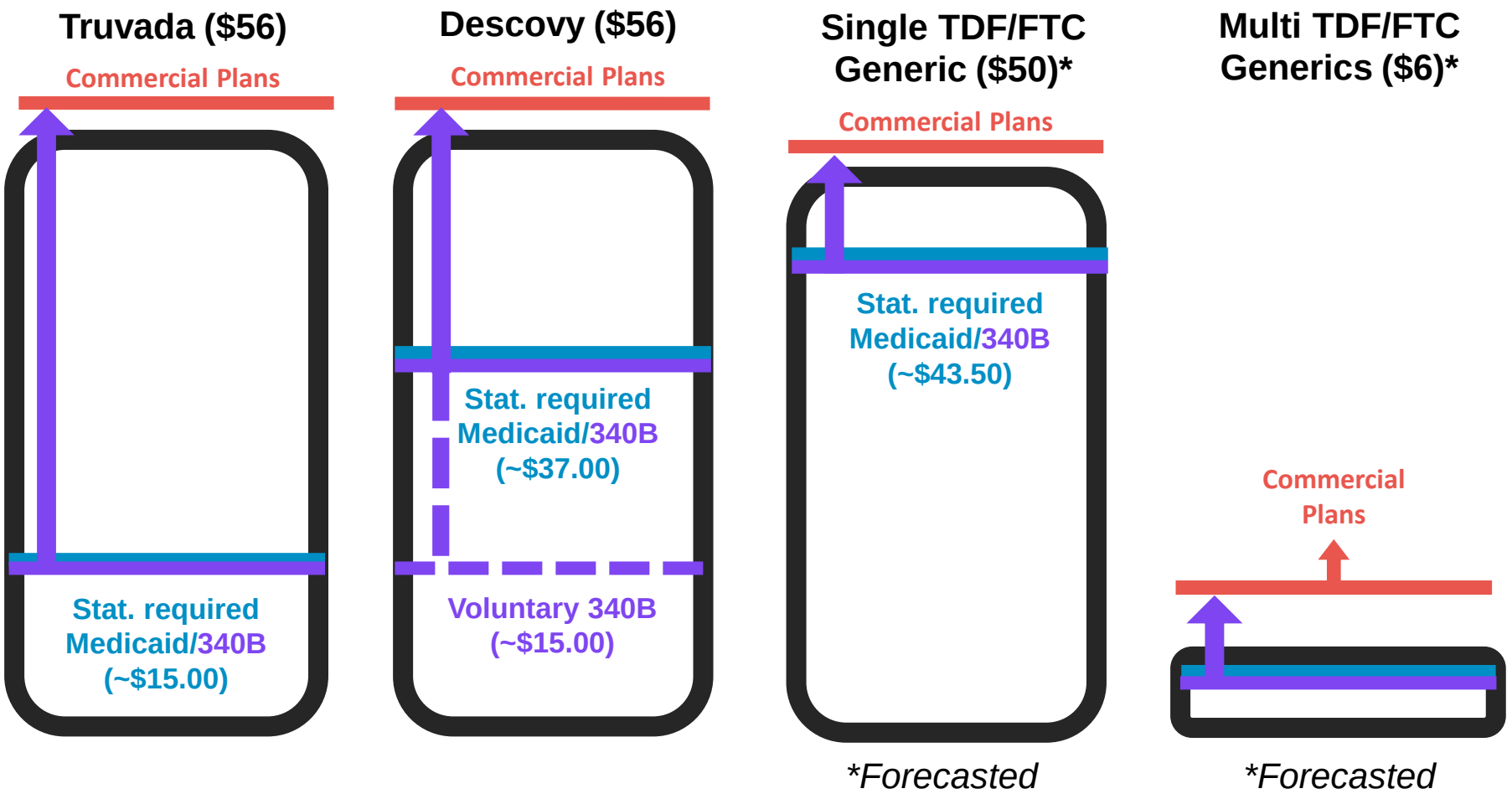
- PrEP is accessed at a range of provider types, including health department STD clinics, pharmacy distribution models, and tele-medicine programs

Next Steps for USPSTF Implementation

- Anticipated CMS/CCIIO and CMS/CMCS guidance to private insurance plans and state Medicaid agencies about appropriate implementation
- Anticipated state insurance regulator bulletins and guidance to plans (e.g., NY Department of Insurance Bulletin on non-discriminatory practices for PrEP coverage)
- Provider and consumer education is critical to ensure that USPSTF and CDC guidelines are being followed and to ensure consumers know about new cost-sharing protections

Considerations for Sustainable PrEP Payment and Delivery Models

PrEP Medication Pricing Changes



Considerations Moving Forward

- Do we need to rethink our current PrEP models in light of changes to the PrEP medication landscape?
- How do we make sure that PrEP is getting to the right places and people, while also designing a cost-effective delivery model? Are those two priorities in tension?
- How should we prepare to engage community health centers given their central role in PrEP expansion as part of the ETE 2030 initiative?
- How should the community respond to formulary designs that preference certain forms of PrEP over others based on cost?

Resources

- Amy Killelea, NASTAD (akillelea@nastad.org
- NASTAD PrEP Resources, https://www.nastad.org/prepcost-resources/additional-resources
- AIDVu PrEP Mapping, https://aidsvu.org/prep/
- CDC PrEP Guidelines, https://www.cdc.gov/hiv/risk/prep/index.html